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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,340	02/19/2002	Hidekazu Shodai	YAM 2 0009	3665

7590 09/17/2008

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
09/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/914,340	SHODAI ET AL.	
	Examiner	Art Unit	
	S. Tran	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-8 and 10-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-8 and 10-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/18/08 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 7, 12-17, 19-24, 27-30 and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebert et al. GB 2151201 A, in view of Monte US 5,578,336 and Brox US 4,780,316.

Ebert teaches a chewable soft gelatin capsule comprising confectionary fill material (abstract; and page 2, lines 40-47). The filled capsule is dried over a length of time until the desired chewing characteristics are attained (abstract; page 2, last paragraph; and examples). The capsule shell comprises gelatin, and plasticizer such

as glycerin or sorbitol (page 1, last paragraph through page 2, paragraphs 1-5). The shell further comprises flavoring agent, and taste modifier (page 2, lines 33-35).

Ebert does not explicitly teach the claimed confectionary fill material.

Monte teaches a confectionary composition useful for the delivery of active agents, the composition comprising chocolate candy consisting mainly of roasted cacao beans, cacao butter, and sugar (abstract; column 5, lines 66 through column 6, lines 1-9; and example 29). Monte further teaches active agents include vitamins, enzymes, phytochemicals, and alimentary vegetable compositions are incorporated in the confection core (column 5, lines 30-35; and example 29). Thus, it would have been obvious to one of ordinary skill in the art to modify the chewable soft capsule of Ebert to include the confectionary composition of Monte to obtain the claimed invention, because Monte teaches using chewable confectionary composition as a carrier for drugs, because Monte teaches chewable confectionary such as chocolate candy is known in pharmaceutical art, and because Ebert teaches the use of confectionary composition as a fill material suitable for the delivery of active agents.

It is noted that Ebert does not expressly teach the claimed drying temperature. However, absent of evidence to the contrary, the burden is shifted to applicant to show that Ebert does not teach dry the capsule under the claimed temperature. This is because Ebert teaches drying the soft gelatin capsule to obtain characteristics. It is noted that Ebert teaches an improved chewable soft gelatin capsule having the properties desired by the applicant, *e.g.*, normal chewing consistency over an extended period of time (page 1, lines 35-37), and avoidance of unpleasant taste (page 1, 2nd

paragraph). However, to be more specific, Brox is cited for the teaching of storing (aging) soft gelatin capsule under temperature of 20°C, 30°C, and 40°C for one month to obtain a chewable capsule having suitable hardness (abstract; and column 5, lines 15-20). Therefore, it would have been obvious to one of ordinary skill in the art to age the soft capsule of Ebert at 30°C and 40°C in view of the teaching of Brox, because Brox teaches that it is well known to store soft gelatin capsule under such temperature to achieve suitable capsule shell hardness, and because Ebert teaches the desirability to obtain soft gelatin capsule having improved characteristics.

Claims 1, 4-7, 11, 12, 15-17, 19-30 and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebert et al. GB 2151201 A, in view of Cavanak US 5,639,724 and Brox US 4,780,316.

Ebert and Brox are relied upon for the reason stated above. Ebert does not explicitly teach the claimed filling material.

Cavanak teaches a confectionary composition comprising vegetable fats, and a drug such as cyclosporin (abstract; column 13, lines 7-26; and example 5). Vegetable fats include cacao fat, cacao butter, conventional chocolate bases, couverture chocolate, and mixtures thereof (ID). Example 5 discloses the claimed percent amounts of chocolate in the composition. Thus, it would have been obvious to one of ordinary skill in the art to modify the capsule of Ebert to include the chocolate-cyclosporin candy in view of the teaching of Cavanak, because Cavanak teaches incorporating drug into chocolate base is known in pharmaceutical art, because Cavanak teaches a chocolate

candy comprising cyclosporin to achieve acceptable taste (column 3, lines 41-45), and because Ebert teaches the use of confectionary as a fill material suitable for the delivery of a wide variety of drugs.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ebert et al. GB 2151201 A, in view of Monte US 5,578,336 or Cavanak US 5,639,724, and Nishizawa et al. US 4,463,024.

Ebert in view of Monte or Cavanak are relied upon for the reasons stated above. Monte and Cavanak do not teach bitter chocolate.

Nishizawa teaches a flavoring composition comprising chocolate including bitter chocolate (example 18). Thus, it would have been obvious to one of ordinary skill in the art to include bitter chocolate to the chocolate composition of Monte or Cavanak to obtain the in view of the teaching of Nishizawa, because Nishizawa teaches using bitter chocolate from cacao bean to obtain a superior flavoring composition, because Monte and Cavanak teaches the use of chocolate including cacao bean.

Claims 1, 4-7, 11, 12, 15-17, 19, 20, 22, 24-30 and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lech US 6,027,746, in view of Cavanak US 5,639,724.

Lech teaches a chewable soft gelatin capsule comprising a solid or liquid fill material (abstract; and column 2, lines 48-50). The fill material comprises flavors, sweeteners, and other food-grade excipient including oils and fats fillers (column 3, lines

1-4; and column 4, lines 66 through column 5, lines 1-17). Lech further teaches the filled capsule is stored at temperature 30°C, 40°C and 50°C for an extended period of time (aging) (column 7, lines 28-30).

Lech does not expressly teach the claimed fill material.

Cavanak teaches a confectionary composition comprising vegetable fats, and a drug such as cyclosporin (abstract; column 13, lines 7-26; and example 5). Vegetable fats include cacao fat, cacao butter, conventional chocolate bases, couverture chocolate, and mixtures thereof (ID). Example 5 discloses the claimed percent amounts of chocolate in the composition. Thus, it would have been obvious to one of ordinary skill in the art to modify the capsule of Lech to include the chocolate-cyclosporin candy in view of the teaching of Cavanak, because Cavanak teaches it is well known in pharmaceutical art to use vegetable fat including chocolate base as a fill material for oral dosage form, (column 3, lines 41-45), and because Lech teaches the desirability to use fill materials comprise flavors, sweeteners, and fats to obtain a suitable oral dosage form.

Claims 8, 12-16 and 31-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lech US 6,027,746, in view of Cavanak US 5,639,724 and Katsuragi et al. US 5,756,543.

Lech and Cavanak are relied upon for the reason stated above. Lech does not teach fats include lard, coconut oil, or polyethylene glycol.

Katsuragi teaches a bitterness-relieving agent comprising fats including vegetable and animal fats such as coconut oil, lard, and the like, and combination there

of (abstract; and column 4, lines 12-30). Thus, it would have been obvious to one of ordinary skill in the art to modify the capsule fill of Lech to include coconut oil, lard, and polyethylene glycol as a fat in view of the teaching of Katsuragi, because Katsuragi teaches the use of these fats in a composition to mask the taste of bitter drugs, and because Lech teaches the desirability to use fat as a fill material to obtain a suitable chewable capsule in which the bitter taste of drug has been masked.

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lech in view of Mehta US 5,084,278.

Lech is relied upon for the reason stated above. Lech does not explicitly teach the flavoring agent such as chocolate flavor.

Mehta teaches a chewable taste mask capsule comprising a fill composition containing sweetening agent, and flavoring agent includes chocolate flavor (column 9, lines 46 through column 10, lines 1-15). Thus, it would have been obvious for one of ordinary skill in the art to include chocolate flavor in the fill material of Lech, because Mehta teaches the use chocolate flavor in chewable dosage form is preferable, and because Lech teaches the desirability to include a wide variety of flavors useful to obtain a chewable dosage form.

Response to Arguments

Applicant's arguments filed 06/18/08 have been fully considered but they are not persuasive.

Applicant argues that Brox does not teach a “regular” storage temperature that is commonly used. Please note that in Examples 5 and 6, Brox stored at 20°C for at least 9.8 months; see col. 4, lines 28-63. Please note as well that 30°C, 35°C, and 40°C are equal to 86°F, 95°F, and 104°F, respectively. These two facts suggest that Brox stored at 30°C and 40°C to speed up his test results, not because they are "regular" storage temperatures, and that storage at 20°C is "normal". In other words, Brox does not provide motivation to store at the claimed temperature range. Applicants are not aware of any soft chewable capsules that generally require storage at elevated temperatures such as 86°F-104°F. While such temperatures might occur due to weather conditions, these conditions cannot be controlled, so the claimed capsules would not be consistently, reliably produced as they can be when part of the manufacturing process. If storage at elevated temperatures such as 30°C-40°C does occur, Applicants submit that it is accidental, rather than intentional. Accident cannot be considered motivation to arrive at the claimed product.

However, in response to applicant’s argument, storage condition at 30°C or 40°C is “regular” and normal. See for example, Weisman et al., Haan et al., and Mehta et al., for the teachings of storage condition at 40°C is well known in the art, And not accidental.

In response to applicant's argument that there is no suggestion to combine Ebert and Brox, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the

references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Ebert teaches the desirability to obtain soft gelatin capsule having improved characteristics, while Brox teaches storing soft gelatin capsule under temperatures such as 30°C and 40°C, to achieve suitable capsule shell hardness.

Applicants argues that Lech does not suggest a reason why they should be stored at such temperatures and does not teach the desirability of the instant claims. Coincidence cannot be considered motivation to arrive at the claimed product.

However, in response to applicant's argument, it is noted that Lech clearly teaches the filled capsule is stored at temperature 30°C, 40°C and 50°C for an extended period of time at column 7, lines 28-30. Coincidence or not, the teaching is there. Therefore, it would have been obvious to one of ordinary skill in the art to, by routine experimentation store the filled capsule under the storage condition taught by Lech. Especially when Lech teaches the use of similar fill materials, such as flavors, sweeteners, and other food-grade excipient including oils and fats fillers (column 3, lines 1-4; and column 4, lines 66 through column 5, lines 1-17), suitable for capsule having the claimed characteristics, such as soft and chewable.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1618